EXHIBIT H

EXHIBIT H-1

DANNA MCKITRICK, P.C.
ATTORNEYS AT LAW

7701 Forsyth Blvd., Suite 1200
St. Louis, MO 63105
314.726.1000
636.946.2203
f 314.725.6592

Jeffrey R. Schmitt
Direct: 314.889.7189
E-Mail: jschmitt@dmfirm.com

November 9, 2020

VIA EMAIL (bstellpflug@goldenberglaw.com)
Benjamin Stellpflug, Esq.
Goldenberg Law, PLLC
800 LaSalle Ave., Suite 2150
Minneapolis, MN 55401

RE: Subpoena to Jost Chemical Co.
In re: Valsartan, Losartan, and Ibesartan Products Liability Litigation
No. 1:19-md-2875-RBK-JS

Dear Benjamin:

As you know, I represent Jost Chemical Co. ("Jost"). We received your subpoena in the above-referenced litigation directed to Jost. As I discussed with your office by phone, I am in the process of working with my client to determine what documents Jost may possess that would be responsive to your subpoena. We appreciate your patience as we complete the process.

However, we are troubled by the breadth and scope of the subpoena. The subpoena requests that Jost produce documents from forty-six (46) different requests across eleven (11) categories of documents stretching back for a period of eight (8) years. Given the sheer magnitude of the subpoena, the time and resources required to research every category for potentially responsive documents, and then prepare them for production, would impose an undue burden on my client, which is not otherwise involved in this litigation in any way. Therefore, we must object to the subpoena on the grounds that it is overbroad and places an undue burden on my client.

It is my understanding that you are willing to accept production of any responsive documents via mail or electronically. If not, then we must also object to producing the documents at your offices in Minneapolis, which is over five hundred miles away from Jost's office in St. Louis, Missouri.

Thank you for your cooperation.

Sincerely,

JEFFREY R. SCHMITT

JS:saa

4822-2649-2369, v. 1

EXHIBIT H-2

Donald R. McMinn
dir 202 898 5875
dmcminn@hollingsworthllp.com

November 9, 2020

By Electronic Mail and First-Class Mail

Marlene J. Goldenberg, Esq.
GoldenbergLaw, PLLC
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55401
mjgoldenberg@goldenberglaw.com

Re: Objections to Non-Party Subpoena of Novartis Pharmaceutical Corporation; *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, Civil No. 19-2875-RBK-JS (D.N.J.)

Dear Ms. Goldenberg:

On October 27, 2020, you caused Novartis Pharmaceuticals Corporation ("NPC") to be served with a lengthy subpoena with 46 document requests, some with subparts, in connection with *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation* (the "MDL"). NPC is not a party to the MDL. Pursuant to Federal Rule of Civil Procedure 45(d), NPC objects to the entirety of plaintiffs' Subpoena to Produce Documents, Information or Objects or to Permit Inspection of The Premises in a Civil Litigation ("subpoena"), served on October 27, 2020.

I. NO EVIDENCE OF NPC NEXUS TO DEFENDANTS AND TO THE MDL

NPC is not a party to the MDL, yet plaintiffs have served on NPC a subpoena with 46 document requests, many of which have subparts.[1] Plaintiffs have divided their dozens of requests into the following eleven categories: (1) Corporate Organization; (2) Contracts; (3) Communications with relevant parties; (4) ANDA and DMF file documents; (5) Nitrosamine Contamination; (6) Recall Related Documents; (7) Quarantine and/or Destruction of products; (8) Communications with the FDA; (9) Testing Data; (10) Solvent Manufacturing, Recovery, and Recycling; and (11) Toxicology Assessments. *See* Subpoena at 8-11. Many of the requests assume that a defendant in the MDL has contracted with NPC to provide services to that

[1] For example, the first document request in plaintiffs' subpoena has thirteen subparts that scrutinize the corporate organization of NPC.

defendant, such as the request for "[d]ocuments sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management." Subpoena at 8.[2] NPC has no reason to believe that it has been "retained by any Defendant" to the MDL litigation.

NPC is unaware of a nexus between it and the defendants to this litigation, whether as part of a defendant's supply chain or by retention, and certainly no relationship with any defendant that would justify 46 wide-ranging document requests. Where there is no nexus between NPC and the defendants, there can be no relevance to NPC's documents. Where there is no relevance, discovery is not permissible because "the burden or expense of the discovery outweighs its benefit." *Costantino v. City of Atl. City*, No. CV 13-6667 (RBK/JS), 2015 WL 12806490, at *3 (D.N.J. Nov. 4, 2015). As the court noted in *Costantino*, the recipient of a subpoena seeking irrelevant documents "should not have to waste an ounce of effort reviewing documents that have nothing to do with the case."

Upon receipt of this subpoena, NPC looked at the MDL docket and learned that two defendants, Aurobindo Pharma USA and Torrent Pharma, Inc. ("Moving Defendants"), have moved to quash the NPC subpoena, as well as what appear to be identical subpoenas that plaintiffs served on another 11 other non-parties.[3] Another MDL defendant, Teva Pharmaceuticals USA, similarly has moved to quash 18 subpoenas, only two of which overlap with those subject to the Aurobindo/Torrent motion.[4] It appears plaintiffs have served the same one-size-fits-all subpoena upon 28 entities.

II. LIMITS BY THE COURTS ON NON-PARTY DISCOVERY

Even if plaintiffs could cobble together a nexus between NPC and a defendant in this litigation sufficient to support a discovery request to a non-party, the subpoena you served upon NPC in no way reflects the limits imposed by the courts on non-party discovery. Appropriately,

---

[2] For additional examples, see the topics listed under "Communications with Relevant Parties," "ANDA and DMF File Documents," "Nitrosamine Contamination," "Communications with FDA" topics 2 and 3, "Testing Data" topics 1 and 2, "Solvent Manufacturing, Recovery, and Recycling," and "Toxicology Assessments").

[3] *See* Oct. 29, 2020 Mot. by the Aurobindo and Torrent Defs.' to Quash Pls.' Subpoenas, Issued to Alcame Corp., Axis Clinicals, Catalent, Gibralter Lab., Inc., Medical Affairs Co., Meridian Consulting, Novartis Pharmaceutical, Peritt Lab., Rising Pharmaceuticals, SDS Environmental Serv., Sipra Labs Ltd., Toxrox Consulting, LLC**,** ECF No. 608 ("Moving Defendants' Motion").

[4] *See* Oct. 30, 2020 Teva Defs.' Mot. to Quash Pls.' Third-Party Subpoenas and for Protective Order to Enjoin or Limit Collection of Irrelevant Information by Third-Party Subpoena, ECF No. 609 ("Teva's Motion").

the court's "restriction [on discovery] may be broader when a non-party is the target of discovery." *Spring Pharm., LLC v. Retrophin, Inc.*, No. 18-CV-04553, 2019 WL 3731725, at *3 (E.D. Pa. Aug. 8, 2019) (quoting *Dart Industries Co., Inc. v. Westwood Chemical Co*., 649 F.2d 646) (9th Cir. 1980); *Weinstein v. Brisman*, No. CV183910KMMAH, 2020 WL 1485960, at *6 (D.N.J. Mar. 26, 2020) ("'Generally, courts afford greater protection to non-parties in discovery, and nonparty subpoenas must meet a higher standard of relevance than subpoenas directed toward parties.'") (quoting *Conforti v. St. Joseph's Healthcare Sys., Inc.*, No. 17-50, 2019 WL 3847994, at *2 (D.N.J. Aug. 15, 2019)).

The subpoena served on NPC includes 46 requests before even considering the multiple subparts. Many of those requests are cumulative and duplicative. None of the requests are specific to NPC, nor do they identify specific relevant information plaintiffs believe *NPC in particular* has. Plaintiffs' requests are generalized, which apparently is a result of plaintiffs' use of a single set of requests to seek discovery from a diverse group of non-parties. The non-parties identified in the motions to quash vary greatly in terms of who they are and the roles they play in pharmaceutical regulation, manufacture, distribution or otherwise (Moving Defendants state in their motion that the nonparties are comprised of "vendors, manufacturers, re-labelers, repackagers, and consultants.") *See* Moving Defendants' Motion at 1. Plaintiffs' effort to force multiple differently situated non-parties to answer the same 46, oft ill-fitting document requests demonstrates the impropriety of plaintiffs' attempted non-party discovery.

NPC objects to plaintiffs' subpoena because the Federal Rules of Civil Procedure make clear that discovery must be proportional and plaintiffs' demands are not proportional. Where there is no nexus between the requests, the non-party upon whom they are served, and the litigation in which they are served, there can be no proportionality. *See Walgreens Specialty Pharmacy, LLC v. Atrium Admin. Servs., Inc.*, No. CV 19-12756 (CCC), 2020 WL 6042280, at *2 (D.N.J. Oct. 13, 2020) ("The scope of discovery… is not unlimited and may be circumscribed.") (citations omitted); *see also Claude P. Bamberger Int'l, Inc. v. Rohm & Haas Co*., No. CIV. 96-1041 (WGB), 1998 WL 684263, at *2 (D.N.J. Apr. 1, 1998) ("While the standard of relevancy is a liberal one, it is not so liberal as to allow a party 'to roam in shadow zones of relevancy and to explore matter which does not appear germane merely on the theory that it might become so.'" (citations omitted)); *see also Costantino v. City of Atl. City*, No. CV 13-6667 (RBK/JS), 2015 WL 12806490, at *3 (D.N.J. Nov. 4, 2015) ("A third-party subpoena … is subject to the limitations of Rule 26.") (internal citation omitted).

NPC objects to plaintiffs' subpoena as unduly burdensome. A subpoena constitutes an undue burden when the burden of compliance outweighs the "value of the information to the serving party." *Spring Pharm., LLC v. Retrophin, Inc.*, No. 18-CV-04553 at *3 (quoting *Moon v. SCP Pool Corp*., 232 F.R.D. 633, 637 (C.D. Cal. 2005) (internal citations omitted)). Courts have determined that there is special weight for the "unwanted burden" placed on non-parties. *Id*. (internal citations omitted).

Plaintiffs' subpoena violates the protections afforded by the Federal Rules. At 46 requests – before accounting for sub-parts – plaintiffs' document requests are burdensomely numerous. Plaintiffs wrote broadly worded requests that, on their face, extend to large categories of documents and, by their lack of specificity, they would require NPC to review huge tranches of materials.[5] Other times, the definitions used by plaintiffs make the requests broader than they might appear on first reading.[6] And plaintiffs request documents spanning an eight-year period, further increasing the volume of materials that NPC would need to review. Frankly, with no background in the litigation and no knowledge of why plaintiffs are seeking all of this information, NPC is not even in position to determine the full extent to which each of plaintiffs' requests is objectionable.

NPC reserves all rights with regard to its objection and opposition to plaintiffs' subpoena, including the right to object to any revised subpoena plaintiffs might consider serving, and to request that plaintiff bear the significant expense associated with any possible production. We are available to confer as necessary regarding these objections, the subpoena, and why plaintiffs apparently believe NPC may have, for instance, been "retained by any Defendant."

Sincerely,

Donald R. McMinn

[5] For example, plaintiffs' request for documents related to Sartans recalls, recall decisions, destruction and disposal of ARB drugs or API, recall letters and notices, and return authorizations related to Sartans product is unduly burdensome.

[6] Plaintiffs define "API" as "any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product." A company like NPC works with hundreds, if not thousands of APIs, of which valsartan is just one. The subpoena also seeks documents from, among others, all employees, agents and all affiliated entities without restriction. The subpoena also impermissibly and over broadly seeks foreign documents, including those related to foreign regulatory agencies.

EXHIBIT H-3

Donald R. McMinn
dir 202 898 5875
dmcminn@hollingsworthllp.com

November 13, 2020

By Electronic Mail and First-Class Mail

Marlene J. Goldenberg, Esq.
GoldenbergLaw, PLLC
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55401
mjgoldenberg@goldenberglaw.com

Re: Objection to Non-Party Subpoena served on Novartis Pharmaceutical Corporation; *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation,* Civil No. 19-2875-RBK-JS (D.N.J.)

Dear Ms. Goldenberg:

On November 12, 2020, you served Novartis Pharmaceuticals Corporation ("NPC") with a subpoena nearly identical to the subpoena you served on "Novartis Pharmaceuticals, [sic] Corporation" on October 27, 2020, in connection with *In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation* (the "MDL"). It appears that the only differences between the original subpoena and the more recent one are the November 12, 2020 service date and the elimination of the comma separating "Pharmaceutical" and "Corporation."

NPC, a non-party to the MDL, incorporates by reference the objections it served on you by email and first-class mail on November 9, 2020. *See* Nov. 9, 2020 Objections to Non-Party Subpoena of Novartis Pharmaceutical Corporation ("NPC's First Objection Letter"). Pursuant to Federal Rule of Civil Procedure 45(d), NPC objects to the entirety of plaintiffs' Subpoena to Produce Documents, Information or Objects or to Permit Inspection of the Premises in a Civil Litigation ("subpoena"), served on November 12, 2020.

NPC also objects to plaintiffs' demand that NPC produce documents on a Sunday a mere three days after service; plaintiffs served this subpoena on Thursday, November 12, 2020, and plaintiffs set the return on Sunday, November 15, 2020. Subpoena at 1.

NPC reserves all of its rights with regard to its objection and opposition to both of plaintiffs' subpoenas, including the right to object to any revised subpoenas plaintiffs might consider serving and to demand plaintiffs bear the expense associated with any eventual

production. As we indicated in NPC's objection to plaintiffs' October 27, 2020, subpoena, we are available to confer as necessary.

Sincerely,

Donald R. McMinn

EXHIBIT H-4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	)))))))	No. 1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

NON-PARTY SOLVIAS, INC.'S RESPONSES AND OBJECTIONS TO PLAINTIFFS' SUBPOENA

Pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure and any applicable local Rules, non-party Solvias, Inc. ("Solvias") hereby objects and responds to Plaintiffs' Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action, dated October 15, 2020 (the "Subpoena"), as follows:

GENERAL OBJECTIONS

1. Solvias objects to the Instructions, Definitions, and Document Requests (the "Requests") to the extent that they seek information that Solvias does not possess or maintain in the ordinary course of its business, and/or purport to impose an obligation on Solvias to locate, obtain, and produce information, documents, and things that are not in the possession, custody, or control of Solvias, including documents or things in the possession, custody, or control of the other parties in this litigation, any non-party affiliates of Solvias, any affiliates of Solvias that have not been served in this action, and any other non-party individuals or entities. Solvias responds to the Subpoena on behalf of itself and not on behalf of any subsidiaries, affiliates, or other corporations or separate legal entities, or any other individuals.

2. Undersigned counsel has informed Plaintiffs' counsel that Solvias does not have possession, custody or control over documents responsive to this Subpoena.

3. Solvias objects to the Subpoena and to each Definition, Instruction, and Request

contained therein to the extent they require Solvias, a non-party, to produce documents or provide information that is within the custody, possession, or control of named Defendants in *In re: Valsartan, Losartan, and Ibersartan Products Liability Litigation*, No. 1:19-md-2875 (the "Underlying Litigation"), or that is unreasonably cumulative or duplicative of documents or information obtained from other parties in discovery.

4. Solvias objects to the Instructions and Definitions and any Requests to the extent that they purport to impose obligations beyond, or otherwise inconsistent with, the Federal Rules of Civil Procedure, the Local Rules of this Court, any Order of this Court, or any other applicable law or rule.

5. Solvias objects to the Subpoena to the extent it seeks proprietary or confidential business information, trade secrets, information protected by privacy laws, or other sensitive information, or documents that contain information that is non-responsive to the Subpoena.

6. Solvias objects to the Subpoena to the extent that it seeks information that is subject to the attorney-client privilege, the work product privilege, the joint defense privilege, and/or any other applicable privilege or protection. Solvias does not waive, intends to preserve, and is preserving the attorney-client privilege, the work-product privilege, the joint defense privilege, and every other applicable privilege or protection with respect to any information protected by such a privilege or protection. The inadvertent production of any documents that are privileged or otherwise protected from disclosure shall not be deemed to be a waiver, in whole or in part, of any privilege or protection applicable to any such documents. Any privileged or protected document that is inadvertently produced shall be returned to Solvias immediately upon Solvias's request, and information derived solely from any such document shall not be used by any party in any manner whatsoever.

7. Solvias objects to the Subpoena to the extent that it is overbroad, vague and ambiguous, duplicative, seeks the production of documents that are neither relevant to the claim or defense of any party in the Underlying Litigation, nor reasonably calculated to lead to the discovery of admissible evidence, nor seeks to impose undue burden and expense.

8. Solvias objects to the Subpoena to the extent that it is not limited to the time period that is relevant to the Underlying Litigation.

9. Neither this response to the Subpoena, nor the production of documents by Solvias, shall be interpreted to concede the truth of any factual assertion or implication contained in the Subpoena.

10. Solvias does not waive, intends to preserve, and is preserving all of its rights to assert that any and all documents, if any, that it may produce in response to the Subpoena are confidential and proprietary. Documents produced by Solvias shall only be used in connection with the Underlying Litigation and shall not be disclosed, in whole or in part, to any person or entity that is not a party to the Underlying Litigation.

11. Solvias reserves the right to modify or supplement its responses and objections to the Subpoena to conform to the results of any continuing discovery. Solvias's responses to the Subpoena in no way constitute an admission or acknowledgement by Solvias as to the relevance, materiality or admissibility of any of these issues or the information contained there, and Solvias expressly reserves its rights to object as such.

12. Solvias objects to the Subpoena to the extent it purports to demand "all," "every," "any," or "each" document(s) pertaining to a particular subject because Plaintiffs have failed to identify, with reasonable particularity, the category or type of documents it is seeking, and thus the Subpoena is overly broad and unduly burdensome.

13. Solvias objects to any Definitions provided by Plaintiffs to the extent those Definitions do not comport with the definitions as provided for in the Federal Rules of Civil Procedure.

RESPONSES AND SPECIFIC OBJECTIONS TO REQUESTS FOR PRODUCTION

Solvias hereby incorporates all General Objections stated above into each and every response to the Requests below as if set forth fully therein.

I. Corporate Organization

REQUEST FOR DOCUMENT NO. 1: All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should ·be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/ or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/ or destruction of recalled and/ or withdrawn Sartan products, (12) tracking of Sartan recall information/ data, (13) storage of recalled Sartan products.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation.

II. Contracts

REQUEST FOR DOCUMENT NO. 1: Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome

because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 2: Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 3: Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

III. Communications with Relevant Parties

REQUEST FOR DOCUMENT NO. 1: All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents that are more readily available from other sources, including the parties to Underlying Litigation

REQUEST FOR DOCUMENT NO. 2: A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

a. Date

b. Recipients and/ or Senders of the Communication

c. General Subject Matter

d. Basis of Privilege

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents that are more readily available from other sources including the parties to Underlying Litigation.

IV. ANDA and DMF File Documents

REQUEST FOR DOCUMENT NO. 1: All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

V. Nitrosamine Contamination

REQUEST FOR DOCUMENT NO. 1: All communications between you and any Defendant relating to nitrosamines.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 2: All communications between you and any Defendant concerning any toxicology assessment.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 3: All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 4: All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.

RESPONSE TO REQUEST FOR DOCUMENT NO. 4:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 5: All reports and/or draft reports provided to you regarding the nitrosamine investigation.

RESPONSE TO REQUEST FOR DOCUMENT NO. 5:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 6: All draft reports edited by you for the comment and provided to any Defendant.

RESPONSE TO REQUEST FOR DOCUMENT NO. 6:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 7: All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.

RESPONSE TO REQUEST FOR DOCUMENT NO. 7:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 8: All testing protocols used by you to test for the presence of nitrosamines in any drug.

RESPONSE TO REQUEST FOR DOCUMENT NO. 8:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome, including because it requests documents unrelated to any claim or defense in this Underlying Litigation.

REQUEST FOR DOCUMENT NO. 9: All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.

RESPONSE TO REQUEST FOR DOCUMENT NO. 9:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 1: All documents or communications relating to nitrosamine testing of any drug

RESPONSE TO REQUEST FOR DOCUMENT NO. 10:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or

that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

VI. Recall-Related Documents

REQUEST FOR DOCUMENT NO. 1: All documents relating to the decision on whether to recall or not to recall any ARBs API.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 2: All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 3: All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome

because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 4: All return authorization documents and/or communications received by You related to any and all Sartan products.

RESPONSE TO REQUEST FOR DOCUMENT NO. 4:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

VII. Quarantine and/or Destruction

REQUEST FOR DOCUMENT NO. 1: All documents and/ or communications concerning the storage of recalled and/or withdrawn ARB products or API.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 2: All documents and/or communications concerning the preservation of contaminated, recalled, and/ or withdrawn ARB products or API.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 3: All documents and/or communications concerning the method of disposing or destroying ARB products or API.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 4: All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.

RESPONSE TO REQUEST FOR DOCUMENT NO. 4:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

REQUEST FOR DOCUMENT NO. 5: All destruction certifications created related to any ARB products or API.

RESPONSE TO REQUEST FOR DOCUMENT NO. 5:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation.

VIII. Communications with the FDA

REQUEST FOR DOCUMENT NO. 1: All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome, because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources.

REQUEST FOR DOCUMENT NO. 2: All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 3: All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 4: All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.

RESPONSE TO REQUEST FOR DOCUMENT NO. 4:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 5: All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.

RESPONSE TO REQUEST FOR DOCUMENT NO. 5:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 6: Documents sufficient to show all meetings, and/ or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

RESPONSE TO REQUEST FOR DOCUMENT NO. 6:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or

that are more readily available from other sources. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

IX. Testing Data

REQUEST FOR DOCUMENT NO. 1: Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 2: All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 3: Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome

because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 4: All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

RESPONSE TO REQUEST FOR DOCUMENT NO. 4:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests. Solvias further objects to the term "Relevant Party" as vague and ambiguous

X. Solvent Manufacturing, Recovery, and Recycling

REQUEST FOR DOCUMENT NO. 1: All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias further objects to the term "SOP" as vague and ambiguous.

REQUEST FOR DOCUMENT NO. 2: Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 3: Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 4: Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

RESPONSE TO REQUEST FOR DOCUMENT NO. 4:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 5: Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.

RESPONSE TO REQUEST FOR DOCUMENT NO. 5:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 6: Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

RESPONSE TO REQUEST FOR DOCUMENT NO. 6:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

XI. Toxicology Assessments

REQUEST FOR DOCUMENT NO. 1: All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.

RESPONSE TO REQUEST FOR DOCUMENT NO. 1:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome

because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 2: All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API.

RESPONSE TO REQUEST FOR DOCUMENT NO. 2:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 3: All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.

RESPONSE TO REQUEST FOR DOCUMENT NO. 3:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation or that are more readily available from other sources, including the parties to Underlying Litigation. Solvias also objects to this Request as duplicative of Plaintiffs' other Requests.

REQUEST FOR DOCUMENT NO. 4: All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

RESPONSE TO REQUEST FOR DOCUMENT NO. 4:

Solvias objects to this Request because it seeks documents outside Solvias's possession, custody, or control. Solvias also objects to this Request as overly broad and unduly burdensome because it requests documents unrelated to any claim or defense in this Underlying Litigation.

Dated: November 20, 2020

Respectfully submitted,

/s/ Sydney L. Schneider

Martin L. Roth, P.C.
Sydney L. Schneider
Kirkland & Ellis LLP
300 North LaSalle
Chicago, IL 60654
Telephone: 312-862-2000
Fax: 312-862-2000
martin.roth@kirkland.com
sydney.schneider@kirkland.com

Attorneys for Solvias, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of November 2020, I caused a copy of the foregoing document to be sent via electronic mail to the following counsel of record:

Marlene J. Goldenberg
Benjamin C. Stellpflug
GoldenbergLaw, PLLC
mjgoldenberg@goldenberglaw.com
bstellpflug@goldenberglaw.com

/s/ Sydney L. Schneider
Sydney L. Schneider

EXHIBIT H-5

IN UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re: Valsartan, Losartan, and Ibesartan Products Liability Litigation	No. 1:19-md-2875-RBK-JS **OBJECTION OF NON-PARTY AXIS CLINICALS, LLC TO PLAINTIFFS' SUBPOENA TO PRODUCE DOCUMENTS**

INTRODUCTION

Pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure, non-party Axis Clinicals, LLC, ("Axis") provides the following Objection to Plaintiffs' subpoena to produce documents, information, or objects or to permit inspection of premises in a civil action, dated October 15, 2020, ("Subpoena"), related to the *In re: Valsartan, Losartan, and Ibesartan Products Liability Litigation*, No. 1:19-md-2875-RBK-JS (the "Litigation").

OBJECTIONS

1. Axis objects to the Subpoena in that while it purposes to have been served upon Axis Clinicals, **LTD**, 1711 Highway 10 East, Dilworth, Minnesota 56304, Axis Clinicals, **LTD** does not do business such location, but instead Axis Clinicals, **LLC**, is the party that does business at such location. As Axis Clinicals, **LLC** has technically not been served, it is not obligated to respond. Notwithstanding the foregoing, even if Axis Clinicals, **LLC** were to waive this defect, Axis Clinicals, **LLC** would still object to the same on the additional grounds set forth below.

2. Axis objects to the Subpoena in that it requires production of documents in Minneapolis, MN in violation of Federal Rule of Civil Procedure 45(c)(2)(A).

3. Axis objects to the Subpoena under Federal Rule of Civil Procedure 45(d)(1) to the extent Plaintiffs did not take or has not taken reasonable steps to avoid imposing undue burden and significant expense on Axis. See also F.R. Civ. P. 45(d)(2)(B)(ii).

4. Axis objects to the Subpoena in its entirety to the extent that its purports to impose obligations upon them that exceed those set forth in Federal Rules 26, 34, and 45, any applicable Local Rules, any Scheduling Order entered in this case, or any other applicable statute, rule, or order.

5. No objection or limitation, or lack thereof, or statement that Axis will produce documents made in these responses and objections constitutes an admission as to the existence of non-existence of documents or information by Axis.

6. Axis objects to the Subpoena in its entirety to the extent that it is duplicative of document requests or subpoenas served by other parties or on other parties or non-parties in the above captioned case.

7. Axis's responses and objections to the Subpoena or its production of any documents shall not be construed as: (i) an admission as to the relevance, admissibility, or materiality of any such documents or their subject matter; (ii) a waiver or abridgement of any applicable privilege; or, (iii) an agreement that requests for similar documents will be treated similarly.

8. Axis reserves all of its rights, including its right to supplement, amend, or correct any of its responses and objections to the Subpoena and its right to object to the admissibility of any part of any document produced in response to any Request or information contained in any such document.

9. Axis objects to the Subpoena under Federal Rule of Civil Procedure 45(c)(3)(A)(iii) to the extent the Subpoena requires disclosure of privileged or other protected matters, including materials protected by any applicable protective order in this case and others.

10. Axis objects to the Subpoena under Federal Rule of Civil Procedure 45(c)(3)(A)(iv) to the extent the Subpoena subjects Axis to undue burden by requiring it to search its records for materials that have no relationship to this case, are not reasonably calculated to lead to admissible evidence, and/or the production of which might require the consent of numerous additional third parties including non-subpoenaed, non-parties. Among other things, and without limitation, to the best of its knowledge, Axis has not had a relationship with any Defendants in relation to Sartan or ARB.

11. Axis objects to the Subpoena to the extent that any definition or instruction contained therein attempts to impose obligations extending beyond those required or authorized by the Federal Rules of Civil Procedure, the Federal Rules of Evidence, the Court's Local Rules, or the Court's Scheduling Order if any or any other applicable order, statute, or regulation.

12. Axis objects to the Subpoena to the extent that any document request, definition, or instruction contained therein seeks, or could be construed to seek, information that is within the scope of the attorney-client privilege, the work-product doctrine, the common-interest privilege, or any other applicable privilege, protection, or immunity from discovery as recognized by any applicable law. Axis does not intend to provide such protected information. Any inadvertent disclosure of any such protected information is not to be deemed a waiver, and Axis expressly reserves the right to object to the introduction at trial or other use of any such protected information that may be inadvertently disclosed.

13. Axis objects to the Subpoena to the extent that any document request therein seeks information that is neither relevant to any claim or defense of any party in the Litigation, nor reasonably calculated to lead to the discovery of admissible evidence with respect to any such claim or defense.

14. Axis objects to the Subpoena to the extent that any document request therein is overly broad, unduly burdensome, vague, indefinite, ambiguous, or fails to describe the information sought with the required reasonable particularity, or is calculated, or would operate, to annoy, embarrass, oppress, or unduly cause expense to Axis.

15. Axis objects to the Subpoena on the basis that in many respects Axis can do no more than guess as to the information which is being sought to be produced. Trying to search, reconstruct, and review files for documents that have no temporal limitation whatsoever is extremely burdensome, time-consuming, labor intensive and expensive for a non-party.

16. Axis objects to the Subpoena to the extent that any document request therein is unreasonably cumulative, redundant, or duplicative of other document requests.

17. Axis objects to the Subpoena as unduly burdensome to the extent it fails to allow Axis a reasonable amount of time in which to search for and gather documents and information responsive to the Subpoena and because of the scope and volume of documents and information requested.

18. Axis objects to the Subpoena to the extent it seeks information and documents subject to a confidentiality agreement or other duty or obligation of confidentiality to a third party.

19. Axis further objects to the Subpoena to the extent that it seeks information and documents that contain confidential, proprietary, or trade secret information.

20. Axis objects to the Subpoena as unduly burdensome to the extent it seeks production of documents that are in the possession of other non-parties or documents which are equally available or readily ascertainable from some other source that is more convenient, less burdensome, or less expensive.

21. Axis objects to the Subpoena to the extent it seeks information for which the burden or expense of the proposed discovery, or potential harm of disclosure to Axis, outweighs any likely benefit in resolving the issues of the Litigation.

22. Axis objects to the Subpoena to the extent it seeks documents that do not exist or that are not within Axis's possession, custody, or control. Axis further objects to the Subpoena to the extent that any Request therein seeks to impose upon Axis an obligation to investigate or discover information, materials, or documents from third parties or regarding services that are not within the possession, custody, or control of Axis, regardless of whether such information, materials, or documents are equally accessible to other parties or non-parties to the Litigation.

23. Axis objects to the definitions of "Communications" and "Documents" set forth in the Subpoena for production of documents as overly broad and unduly burdensome because that definition includes electronic communications that Axis has no obligation to store or collect, including voice mails, text messages, instant messages, and the like.

Dated this 2nd day of November, 2020.

/s/ Joel M. Fremstad

Joel M. Fremstad (ND # 05541)
FREMSTAD LAW FIRM
P.O. Box 3143
Fargo, ND 58108-3143
Telephone: (701) 478-7620
joel@fremstadlaw.com
ATTORNEYS FOR AXIS CLINICALS, LLC.

EXHIBIT H-6

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	NO:1:19-md-2875-RBK-JS Hon. Robert Kugler Hon. Joel Schneider

AVANTOR PERFORMANCE MATERIALS, LLC'S OBJECTIONS TO SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION OR OBJECTS OR TO PERMIT INSPECTION OF THE PREMISES IN A CIVIL ACTION

Non-party Avantor Performance Materials, LLC, improperly identified as "Avantor," hereby states its objections to Plaintiffs' Subpoena to Produce Documents, Information or Objects or to Permit Inspection of the Premises in a Civil Action ("Subpoena") pursuant to the Federal Rules of Civil Procedure ("Rules").

PRELIMINARY STATEMENT

Under Rule 45(d)(1), a party "must take reasonable steps to avoid imposing undue burden or expense" on a recipient of a subpoena. Plaintiffs have not as yet done so with respect to the Subpoena, which contains about 46 Requests for Production (the "requests")—some with multiple subparts—covering an eight-year time period.

GENERAL OBJECTIONS

These objections shall have the same force and effect as if fully set forth in response to each Request.

1. Avantor objects to the Subpoena to the extent that it seeks to impose on Avantor any obligations beyond those authorized under the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the District of New Jersey (the "Local Rules"), or any orders of the United States District Court for the District of New Jersey (the "Court"), including but not limited to the Order regarding "macro" discovery [303].

2. Avantor objects that the Subpoena improperly names Avantor Performance Materials, LLC as "Avantor," which is not a corporate entity, and states an outdated address in Phillipsburg, NJ 08865.

3. Avantor objects to the Subpoena because the time to comply is unreasonable. The Subpoena's date of compliance is November 15, 2020, but Avantor was not served until November 12, 2020. Three days (including a weekend) to comply is unreasonable.

4. Avantor objects to the Subpoena because it fails to comply with Rule 45(c) and requires production of documents, electronically stored information, or tangible things at a place more than 100 miles of where Avantor resides or regularly transacts business in person. The place of compliance, GoldenbergLaw, PLLC, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401, is more than 1000 miles from Avantor, 222 Red School Lane, Phillipsburg, NJ 08865.

5. Avantor objects to the Subpoena to the extent that it seeks documents or information that are neither relevant to any party's claim or defense nor proportional to the needs of this case because they relate to Avantor, a non-party to this action, and/or they are unrelated to the subject matter of this action.

6. Avantor objects to the Subpoena to the extent that it requires the disclosure of any documents or information that are a matter of public record, are otherwise reasonably available to Plaintiffs, or are already in Plaintiffs' possession, custody, or control.

7. Avantor objects to the Subpoena to the extent that the documents or information requested are obtainable from any party to the above-captioned action. Such documents or information should be obtained from other parties to the action rather than Avantor. Otherwise, the Subpoena is designed to impose an undue burden on Avantor.

8. Avantor objects to the Subpoena to the extent that the documents sought are unreasonably cumulative or duplicative, or are obtainable from a source other than Avantor that is more convenient, less burdensome, or less expensive.

9. Avantor objects to the Subpoena to the extent that the burden or expense of the proposed discovery outweighs its likely benefit.

10. Avantor objects to the Subpoena to the extent that it is overbroad as to time.

11. Avantor objects to each request to the extent that it requires or purports to require Avantor to describe or locate and produce "all" documents or information, which is beyond the requirements of Rule 45. Subject to its objections, and to the extent Avantor agrees to produce any documents or information requested by the Subpoena, Avantor will respond to the Requests by conducting a reasonable search for potentially responsive and non-objectionable documents or information.

12. Avantor objects to each request to the extent that it is so vague, ambiguous, or incomprehensible that Avantor cannot determine what documents or information are sought and therefore cannot provide a meaningful response.

13. To the extent Avantor responds to the Subpoena, Avantor does not in any way waive or intend to waive, but rather intends to preserve and is preserving:

a. all objections as to competency, relevancy, materiality, authenticity, and admissibility;

b. all rights to object on any grounds to the use of any documents in any subsequent proceedings, including trial of this or any other action;

c. all objections as to vagueness and ambiguity;

d. all objections as to overbreadth, burden, oppressiveness, or undue hardship; and

e. all rights to object on any ground to any further requests or subpoenas involving or related to any of the requests addressed to Avantor.

14. Avantor reserves the right to object to Plaintiffs' use of any documents at trial or any other proceeding, as deemed necessary and appropriate by Avantor.

15. Avantor objects to each request to the extent that it seeks information protected from disclosure by the attorney-client privilege, the attorney work-product doctrine, or any other applicable privileges or immunities. To the extent that any information protected from disclosure by an applicable privilege or immunity is inadvertently provided or identified in response to a request, that is not to be construed as a waiver of the privilege or immunity. Fed. R. Evid. 502(b). An objection based on a privilege, immunity, or other protection should not be construed as a representation that responsive information exists or existed. Such an objection indicates only that the Request is of such a scope as to potentially embrace privileged, immune, or otherwise protected information. In addition, Avantor objects to the extent that Plaintiffs seek or require Avantor to produce a privilege log for documents falling within the attorney-client privilege or attorney work-product doctrine, if such documents were created after the date that this lawsuit was filed. If Avantor notifies Plaintiffs that an inadvertent disclosure has occurred, Plaintiffs must immediately return the inadvertently produced privileged material, including any copies, to Avantor. Further, Plaintiffs must not use or disclose the information and must take reasonable steps to retrieve the information if Plaintiffs disclosed it before being notified or otherwise comply with Rule 45(e)(2)(B). If the production or identification of discovery is deemed by this Court to be a waiver of any privilege or immunity, the waiver shall be a limited waiver pertaining to that discovery only.

16. Avantor objects to each request to the extent that it seeks documents or information reflecting, containing, or derived from confidential personal or proprietary business information, research, or trade secrets belonging to Avantor, its customers, or to any third

parties. Disclosure of this type of information could adversely affect an individual or the competitive business position of Avantor and/or reveal proprietary or confidential information of Avantor, its business partners, or its customers.

17. Avantor objects to each request to the extent that it seeks information that Avantor is precluded from revealing pursuant to confidentiality obligations to third parties.

18. Avantor objects to each request to the extent that it requires or purports to require Avantor to review and produce electronic documents or data that cannot be reviewed in an efficient and cost-effective manner, or to the extent that they seek discovery of electronically stored information from sources that Avantor identifies as not reasonably accessible because of undue burden or cost pursuant to Rule 45(e)(1)(D).

19. To the extent that Avantor provides documents or information or agrees to provide documents or information in response to any request, Avantor does so subject to, and without waiving, any objections or any privileges.

20. By responding or objecting to a request, Avantor does not admit or imply that it may have documents or information responsive to that request.

21. Avantor reserves the right to request an agreement or order requiring Plaintiffs to pay Avantor's costs and attorneys' fees incurred in responding to the Subpoena.

22. Avantor incorporates the foregoing General Objections into each and every specific objection and response to the requests set forth below, regardless of whether the General Objections are referred to therein. From time to time, a specific objection and response may repeat a General Objection for emphasis or some other reason. The failure to include any General Objection into a specific objection and response shall not be interpreted as a waiver or limitation of that objection.

OBJECTIONS TO DEFINITIONS

The following Objections to Definitions are incorporated into each specific objection and response below as if fully repeated therein.

1. Avantor objects to the definitions of "You" and "Your" as not proportional to the needs of the case, overly broad, and unduly burdensome because they include "employees, agents, and officers and any affiliated entity of the answering party." Any response by Avantor will be on behalf of itself only.

2. Avantor objects to the definition of "Documents" as not proportional to the needs of the case, overly broad, unduly burdensome, and seeking inaccessible electronically stored information under Rule 45(e)(1)(D) because it includes "back-up tapes," "back-up or legacy formats, wherever found or maintained," and "originals and copies."

3. Avantor objects to the definition of "Recalled Products" as vague and ambiguous.

4. Avantor objects to the definition of "Regulatory and Regulatory Authority" as not proportional to the needs of the case and overly broad because it includes foreign regulatory agencies.

5. Avantor incorporates the foregoing Objections to Definitions into each and every specific objection and response to the Requests set forth below, regardless of whether the Objections to Definitions are referred to therein. From time to time, a specific objection and response may repeat an Objection to Definition for emphasis or some other reason. The failure to include any Objection to Definition into a specific objection and response shall not be interpreted as a waiver or limitation of that objection.

SPECIFIC OBJECTIONS

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan productions, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) sortation of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claims or defenses. Avantor objects that this request is not proportional to the needs of the case, overly broad, and unduly burdensome.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case, overly broad, and unduly burdensome because it encompasses "ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management."

2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case, overly broad, and unduly burdensome because it encompasses "ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management."

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case

and overly broad because it encompasses "services . . . related to the manufacture of any ARB drug" without any limitation.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "the nitrosamine contamination" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "the nitrosamine contamination" without any limitation.

2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:

(a) Date
(b) Recipients and/or Senders of the Communication
(c) General Subject Matter
(d) Basis of Privilege

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "the nitrosamine contamination" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "the nitrosamine contamination" without any limitation.

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "the filing or supplementation of any Drug Master File to any ARB drug" without any limitation.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "nitrosamines" without any limitation.

2. All communications between you and any Defendant concerning any toxicology assessment.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "any toxicology assessment" without any limitation.

3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the term "the nitrosamine contamination" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "[a]ll communications . . . regarding any Defendant" and "the nitrosamine contamination" without any limitation.

4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB, API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the terms "the nitrosamine investigation" and "warning letter" are vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "the nitrosamine investigation," "warning letter," and "API" without any limitation.

5. All reports and/or draft reports provided to you regarding the nitrosamine investigation.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the term "the nitrosamine investigation" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad.

6. All draft reports edited by you for comment and provided to any Defendant.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "draft reports" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "draft reports" without any limitation.

7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "nitrosamine contamination, any ARB drug, or cGMP compliance" without any limitation.

8. All testing protocols used by you to test for the presence of nitrosamines in any drug.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "[a]ll testing protocols" and "any drug" without any limitation.

9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.

RESPONSE:

Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "any audit" without any limitation.

10. All documents or communications relating to nitrosamine testing of any drug.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "any drug" without any limitation.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "any ARBs API" is vague and confusing.

2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "any . . . API" without any limitation.

3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "recall letters or notices relating to . . . API" without any limitation from this vast population of potential recipients and reviewers.

4. All return authorization documents and/or communications received by You related to any and all Sartan products.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "all return authorization documents" and "any and all Sartan products" without any limitation.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "testing" and "API" without any limitation.

5. All destruction certifications created related to any ARB products or API.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "any ARB API or finished dose drug," "nitrosamine contamination," or "recall" without any limitation.

2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "the nitrosamine contamination" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "the nitrosamine contamination more generally" without any limitation.

3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "the nitrosamine contamination" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "the nitrosamine contamination more generally" without any limitation.

4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "the toxicological assessment of NDMA" and "the nitrosamine impurities" are vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "the nitrosamine impurities" without any limitation.

5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrases "any Relevant Party's," "the FDA's Warning Letter," and "Type B Meeting" are vague and ambiguous. Avantor objects that this request is

not proportional to the needs of the case and overly broad because it encompasses "solvents used to make . . . API" and "the FDA's Warning Letter" without any limitation.

6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "the Nitrosamine contamination" is vague and ambiguous.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the term "testing" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "testing" and "product" without any limitation.

2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrases "AMES testing, DEREK testing and the like" and "the nitrosamine contamination" are vague and ambiguous. Avantor objects that this request

is not proportional to the needs of the case and overly broad because it encompasses "testing" and "any Defendant's drugs" without any limitation.

3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "samples" without any limitation.

4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third Party Laboratory retained by you.

RESPONSE:

Avantor objects that the phrases "Relevant Party" and "Third Party Laboratory" are vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "[a]ll testing" without any limitation. Avantor objects that this request seeks documents not within its possession, custody, or control.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the term "SOPs" is vague and ambiguous. Avantor

objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "any testing" and "API" without any limitation.

4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for ARB.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.

RESPONSE:

Avantor objects that this request is confusing and unintelligible. Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "such API" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API.

RESPONSE:

Avantor objects that this request is confusing and unintelligible. Avantor objects that the phrase "such API" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.

RESPONSE:

Avantor objects that this request is confusing and unintelligible. Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "the nitrosamine impurity" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "any toxicology assessment(s)" and "Defendant's drugs" without any limitation.

4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

RESPONSE:

Avantor objects that this request seeks documents that are not relevant to any party's claim or defense. Avantor objects that the phrase "such API" is vague and ambiguous. Avantor objects that this request is not proportional to the needs of the case and overly broad because it encompasses "API" without any limitation.

Dated: November 24, 2020

s/ Allyson McKinstry

Allyson McKinstry
Crowell & Moring LLP
590 Madison Avenue, 20th Floor
New York, NY 10022-2544
Phone: 212-223-4000
Fax: 212-223-4134

Attorneys for Non-Party Avantor Performance Materials, LLC

CERTIFICATE OF SERVICE

I hereby certify that on November 24, 2020, a true and accurate copy of the foregoing Non-Party Avantor's Objections to Subpoena to Produce Documents, Information or Objects or to Permit Inspection of the Premises in a Civil Action was served via email on counsel of record for Plaintiffs in the above-captioned action:

Marlene J. Goldenberg
GoldenbergLaw, PLLC
800 LaSalle Avenue
Suite 2150
Minneapolis, MN 55401
mjgoldenberg@goldenberglaw.com

Attorney for Plaintiffs

s/ Allyson McKinstry
Allyson McKinstry

EXHIBIT H-7

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IBESARTAN PRODUCTS LIABILITY LITIGATION	)	No. 1:19-md-2875-RBK-JS

OBJECTIONS AND RESPONSES TO SUBPOENA DUCES TECUM

Third party Stericycle, Inc. ("Stericycle"), through the undersigned counsel, hereby respectfully submits the following Objections and Responses to the Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action served by Plaintiff on October 15, 2020 (the "Subpoena").

GENERAL OBJECTIONS

A. Third party Stericycle objects to the Subpoena as overly broad and unduly burdensome in light of Stericycle's limited role in the matters at issue in this litigation. As indicated in greater detail below, many of the Subpoena requests bear no relation to information Stericycle would be likely to have in its possession, custody or control, and plaintiff has made no apparent attempt to tailor its requests to the information Stericycle would be expected to have. In addition, to the extent Stericycle may have responsive information, it would be entirely duplicative of information otherwise available to plaintiff from those entities who are named as parties to this litigation. Finally, the Subpoena is grossly overbroad and unduly burdensome in light of the issues in this case insofar as the Subpoena purports not to be restricted to any reasonable date range.

B. Third party Stericycle further objects to the Subpoena to the extent it seeks documents or information belonging to its client and that may be deemed confidential or proprietary to its client.

C. Third party Stericycle further objects to the Subpoena to the extent it seeks documents or information protected by the attorney-client privilege, work product doctrine, or any similar privilege or doctrine.

OBJECTIONS AND RESPONSES

Stericycle further objects and responds to the specifically-enumerated paragraphs of the Subpoena as follows:

Corporate Organization

1. All documents and/or communications sufficient to identify your employees, agents, or third parties responsible for or involved in the (1) drafting of recall notifications for Sartan products, (2) the dissemination of Sartan recall notifications, (3) compilation of whom recall notifications should be disseminated to, (4) online tracking system for Sartan recalls, (5) receipt of return authorizations, (6) process of recalled and/or withdrawn Sartan products, (7) Sartan audits, (8) Sartan validation, (9) regulatory compliance, (10) soration of Sartan products, (11) disposal and/or destruction of recalled and/or withdrawn Sartan products, (12) tracking of Sartan recall information/data, (13) storage of recalled Sartan products.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played with respect to "drafting" the notice, "compilation of whom recall notifications should be disseminated" and other tasks not performed by Stericycle. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including the agreements relating to the services it performed

in connection with the recall, upon review and execution of an appropriate protective order.

Contracts

1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including the agreements relating to the services it performed in connection with the recall, upon review and execution of an appropriate protective order.

2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to he ARB drug recalls, or recall management.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be

deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including the agreements relating to the services it performed in connection with the recall, upon review and execution of an appropriate protective order.

3. Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including the agreements relating to the services it performed in connection with the recall, upon review and execution of an appropriate protective order.

Communications with Relevant Parties

1. All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, includ9ing any inspection of a facility where any ARB drug is manufactured.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with

the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

2. A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information: (a) Date, (b) Recipients and/or Senders of the Communication, (c) General Subject Matter, (d) Basis of Privilege.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

ANDA and DMF File Documents

1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

Nitrosamine Contamination

1. All communications between you and any Defendant relating to nitrosamines.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

2. All communications between you and any Defendant concerning any toxicology assessment.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

5. All reports and/or draft reports provided to you regarding the nitrosamine investigation.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

6. All draft reports edited by you for comment and provided to any Defendant.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General

Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

8. All testing protocols used by you to test for the presence of nitrosamines in any drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection

with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

10. All documents or communications relating to nitrosamine testing of any drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in recall, whereas Stericycle provided specific, limited services in connection with the recall event. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

Recall-Related Documents

1. All documents relating to the decision on whether to recall or not to recall any ARBs API.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including the agreements relating to the services it performed in connection with the recall, upon review and execution of an appropriate protective order.

2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including documents relating to destruction or disposal of recalled product, upon review and execution of an appropriate protective order.

3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including notices its clients instructed it to send in connection with the recall, upon review and execution of an appropriate protective order.

4. All return authorization documents and/or communications received by Stericycle, Inc. related to any and all Sartan products.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including correspondence located during a reasonable search of its recall event files for these recall events, upon review and execution of an appropriate protective order.

Quarantine and/or Destruction

1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including correspondence located during a reasonable search of its recall event files for these recall events, upon review and execution of an appropriate protective order.

2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including correspondence located during a reasonable search of its recall event files for these recall events, upon review and execution of an appropriate protective order.

3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including correspondence located during a reasonable search of its recall event files for these recall events, upon review and execution of an appropriate protective order.

4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

5. All destruction certifications created relating to any ARB products or API.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, Stericycle will produce non-privileged documents responsive to this request, including correspondence located during a reasonable search of its recall event files for these recall events, upon review and execution of an appropriate protective order.

Communications with the FDA

1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB PII or finished dose drug, nitrosamine contamination, and/or recall.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or nitrosamine contamination more generally.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

6. Documents sufficient to show all meetings, and/or verbal communications had between you and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

Testing Data

1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

2. All testing conducted by you, including ALES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in

connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and [sic] Relevant Party or any Third Party Laboratory retained by you.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

Solvent Manufacturing, Recovery, and Recycling

1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents

that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections,

following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections,

following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

Toxicology Assessments

1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections,

following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.

Stericycle objects to this request as vague, overly broad, and unduly burdensome. Stericycle further objects to this request as misleading regarding the role Stericycle played in the recall, whereas Stericycle provided specific, limited services in connection with the recall event. Stericycle further objects to producing documents that may be deemed confidential or proprietary to Stericycle and/or its client absent a protective order. Subject to, and without waiving, these and the General Objections, following a reasonable search, Stericycle has not located any such documents in Stericycle's possession, custody or control.

Dated: November 16, 2020

Stericycle, Inc.

Michael J. Fanis
Its Vice President and Assistant General Counsel – Litigation